510(k) Summary – K123784

Submitter's Contact Information:

APR 10 2013

Straumann USA, LLC (on behalf of Institut Straumann AG)

60 Minuteman Road

Andover, MA 01810

Phone Number: 1-978-747-2509

Fax Number: 1-978-747-0023

Contact Person: Jennifer M. Jackson, MS

Date of Submission: 07-Dec-2012

Name of the Device:

Trade Name: Straumann® Dental Implant System
SLA®, SLActive® and Roxolid® Product Families

Common Name: Dental Implants

Classification Name: Implant, Endosseous, Root-form

Regulation Number: §872.3640

Predicate Device(s):

K983742, ITI Dental Implants

K012757, ITI® Dental Implant System

K033922, Modification to ITI Dental Implant System

K033984, ITI Dental Implant System

K053088, SLActive Implants

K062129, P.004 Implants

K081419, Modified Dental Implant

K083550, Modified Dental Implant

K111357, Narrow Neck CrossFit (NNC) Ø3.3 mm Dental Implant System

K121131, Straumann Bone Level Ø4.1 mm and Ø4.8 mm Regular Connection (RC) Roxolid Dental Implants

K122855, Straumann Tissue Level Ø4.1 mm and Ø4.8 mm Roxolid Dental Implants

K123784

Traditional 510(k) Submission

Change in Straumann Dental Implant Instructions for Use Structure

Device Description:

This premarket notification serves to affect a labeling change applicable to all endosseous dental implants of the Straumann® Dental Implant System. The subject devices are physically identical to the listed predicate devices. The device descriptions are identical to those presented in the referenced predicate submissions.

The proposed Straumann Implant Instructions for Use (IFU) changes in this premarket notification are to address the following:

- Update the IFU content to reflect the FDA Guidance on Medical Device Patient Labeling regarding contraindications, general warnings, and precautions
- Clarify the term "poor bone metabolism" under contraindications and move the condition "osteoporosis" to Precautions in the IFU
- Modify the indications for use statement previously cleared in premarket notifications K081419 and K083550 to relocate the statement regarding specific indications for small diameter (Ø3.3 mm) implants from the indications for use to the Precautions

Intended Use / Indications For Use:

Straumann® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® Dental implants are also indicated for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments). In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.

Technological Characteristics:

There are no changes to the materials, surface treatments, design, fundamental operating principles, or sterilization processes or procedures as a result of the proposed IFU changes. No new surgical instruments or secondary components are being introduced as a result of the proposed IFU changes.

Performance Testing:

The bench and animal performance testing previously submitted in support of the referenced predicate devices continues to be representative of the performance of the subject devices. A non-interventional clinical study was conducted in accordance with applicable national and local regulations and is being submitted as supporting documentation for the proposed IFU changes.

A review and summarization of the clinical literature associated with the use of dental implants in the presence of metabolic bone diseases was presented. The available data indicate that metabolic disease of the bone is not a strict contraindication for the use of dental implants; the evidence supports that performance of dental implants in patients whose metabolic bone disease is pharmacologically under control is equivalent to those in patients free of metabolic bone disease. This supports the relocation of the statement regarding metabolic bone disease from the Contraindications section of the Instructions For Use to the Precautions section to allow the clinician to determine whether a particular patient is a suitable candidate for dental implants.

A subset of data from a Non-Interventional Study (i.e. post-market) in humans was presented. The study as a whole included subjects with the need of dental implant therapy and restoration according to the cleared indications for the Roxolid Ø3.3 mm implant within Germany, United Kingdom, France, Spain, Sweden, the United States, and Canada. The data subset was specific to patients having implants placed in the molar region of the mouth.

The primary study purpose was to determine implant success and survival rates one year after implant placement. Secondary purposes included assessing the change in bone level (to be estimated by the investigator), success and survival rates 2 and 3 years after implant placement and assessment of other treatment characteristics including loading protocol, implant position, augmentation procedures and clinician satisfaction.

As of the 2-year time point, there were two reports of implant failure in the molar region (one prior to restoration and one prior to the 1-year time point after final restoration - Table 16). There was no implant failure reported following the 1-year follow-up visit in the molar region. Other reported implant related adverse events in the molar region include two cases of inflammation (one at implant placement and one at 2-years), one case of poor implant stability (at implant placement), and one case of peri-implant resorption (at final restoration). All adverse events are known to have resolved with the exception of the report of inflammation at 2-years.

This clinical data suggest that performance of Roxolid Ø3.3 mm implants placed in the molar region is equivalent to those placed in other parts of the mouth. This supports the relocation of the recommendation against using Ø3.3 mm (small diameter) implants in the molar region from the Specific Indications section of the Instructions For Use to the Precautions section to allow the clinician to determine whether application in the molar region is appropriate for the particular patient.

Conclusion:

The subject devices are identical in all respects to the predicate devices identified. This submission only introduces changes to the product labeling. The data and documentation submitted in this premarket notification supports the proposed changes to the Instructions for Use for the Straumann Dental Implant System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 10, 2013

Jennifer M. Jackson, MS
Senior Regulatory Affairs Project Manager
Straumann USA, Limited Liability Company
60 Minuteman Road
ANDOVER MA 01810

Re: K123784
Trade/Device Name: Straumann® Dental Implant System
SLA®, SLActive® and Roxolid® Product Families
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: March 18, 2013
Received: March 19, 2013

Dear Ms. Jackson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer
-S for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123784

Device Name: Straumann® Dental Implant System
SLA®, SLActive® and Roxolid® Product Families

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
2013.04.10
10:13:25 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123784